

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Effect of vitamin D on improvement of left ventricular ejection fraction in patients with systolic heart failure

#### Protocol summary

##### Study aim

Determine the effect of vitamin D on left ventricular ejection fraction in patients with chronic heart failure

##### Design

This clinical trial study is double blinded and parallel. Patients with chronic heart failure are divided into two groups receiving vitamin D as the intervention group and placebo recipient as placebo group and are evaluated for ejection fraction before and after receiving vitamin D and placebo.

##### Settings and conduct

Patients referring to Ayatollah Mousavi Hospital in Zanjan who have been diagnosed with systolic heart failure, have been evaluated the left ventricular ejection fraction and cardiac failure score by using vivid echocardiography and biplane simpson prior before taking the drug. The variables studied are evaluated after 8 weeks of intervention.

##### Participants/Inclusion and exclusion criteria

Inclusion from study: Patients with chronic heart failure with a ejection fraction of less than 45% and greater than 20% (based on Framingham criteria, NYAH Class I, II, III) , Vitamin D levels less than 30 ng / dl, over age 40  
Exclusion from study: Patients with Hypercalcemia, Osteomalacia or Corticosteroid therapy

##### Intervention groups

Individuals with systolic insufficiency are randomly divided into two groups of intervention group and placebo group. To a group, a placebo drug or the appearance of a capsule of vitamin D and to intervention group the natural vitamin D is given, 50,000 units and weekly for 8 weeks. Before taking the medication and 8 weeks after taking the medication, the left ventricular ejection fraction and the heart failure rating based on the NYHA ranking were calculated by vivid echocardiography with Biplane simpson method

##### Main outcome variables

Ejection Fraction changes, end diastolic volume, and heart failure Class

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190410043236N1**

Registration date: **2019-07-08, 1398/04/17**

Registration timing: **retrospective**

Last update: **2019-07-08, 1398/04/17**

Update count: **0**

##### Registration date

2019-07-08, 1398/04/17

##### Registrant information

##### Name

Hamid Khederlou

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 24 3353 4019

##### Email address

ham\_khed@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2016-05-02, 1395/02/13

##### Expected recruitment end date

2017-04-15, 1396/01/26

##### Actual recruitment start date

2016-10-05, 1395/07/14

##### Actual recruitment end date

2018-07-17, 1397/04/26

##### Trial completion date

2018-11-17, 1397/08/26

##### Scientific title

Effect of vitamin D on improvement of left ventricular ejection fraction in patients with systolic heart failure

#### Public title

Effect of vitamin D on improvement of left ventricular ejection fraction in patients with systolic heart failure

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Chronic heart failure with  $20\% \leq EF \leq 45\%$  (based on Framingham criteria, NYAH Class I, II, III) The level of 25 (OH) Vit D is less than 30 ngr / dl Age over 40 years

##### Exclusion criteria:

Hypercalcemia Osteomalacia Taking corticosteroid medication

#### Age

From **40 years** old

#### Gender

Both

#### Phase

2-3

#### Groups that have been masked

- Participant
- Investigator
- Outcome assessor

#### Sample size

Target sample size: **80**

Actual sample size reached: **82**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

In present study, simple randomization method was used.

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

This double-blind study was carried out and the cardiologist who do echocardiography patients, as well as those taking medication or placebo, are blind.

#### Placebo

Used

#### Assignment

Parallel

#### Other design features

### Secondary Ids

empty

### Ethics committees

#### 1

##### Ethics committee

###### Name of ethics committee

Zanjan University of Medical Sciences Ethics Committee

###### Street address

Azad Blv.- Headquarters of Zanjan University of Medical Sciences

#### City

Zanjan

#### Province

Zanjan

#### Postal code

6856568823

#### Approval date

2016-04-14, 1395/01/26

#### Ethics committee reference number

ZUMS.REC.1395.205

### Health conditions studied

#### 1

##### Description of health condition studied

Systolic Heart failure

##### ICD-10 code

I30-I52

##### ICD-10 code description

IX Diseases of the circulatory system

#### 2

##### Description of health condition studied

Systolic Heart failure

##### ICD-10 code

I50.1

##### ICD-10 code description

Left ventricular failure

### Primary outcomes

#### 1

##### Description

Ejection Fraction

##### Timepoint

Before beginning the intervention with vitamin D and placebo and then 2 months after the intervention

##### Method of measurement

Echocardiography

#### 2

##### Description

End Diastolic Volume

##### Timepoint

Before beginning the intervention with vitamin D and placebo and then 2 months after the intervention

##### Method of measurement

Echocardiography

#### 3

##### Description

Heart Failure Class

##### Timepoint

Before beginning the intervention with vitamin D and placebo and then 2 months after the intervention

##### Method of measurement

Echocardiography

## Secondary outcomes

### 1

#### Description

Vitamin D

#### Timepoint

Before the intervention, then two months after the intervention with vitamin D and placebo

#### Method of measurement

High Performance Liquid Chromatography

### 2

#### Description

Albumin

#### Timepoint

Before the intervention, then two months after the intervention with vitamin D and placebo

#### Method of measurement

Immunoassay

### 3

#### Description

Creatinine

#### Timepoint

Before the intervention, then two months after the intervention with vitamin D and placebo

#### Method of measurement

Immunoassay

### 4

#### Description

Calcium

#### Timepoint

Before the intervention, then two months after the intervention with vitamin D and placebo

#### Method of measurement

Ion Selected (Specific) Electrode

### 5

#### Description

Phosphor

#### Timepoint

Before the intervention, then two months after the intervention with vitamin D and placebo

#### Method of measurement

Ion Selected (Specific) Electrode

## Intervention groups

### 1

#### Description

Intervention group: Intervention group: A 50000 unit capsule of vitamin D, manufactured by Abidi company, is given weekly and at 50,000 units for 8 weeks. It should be noted that patients will not be aware of the type of medicine. Patients are monitored for 2 months.

#### Category

Treatment - Drugs

### 2

#### Description

Placebo group: Appearance of 50,000 capsules of vitamin D, manufactured by Abidi company, is given weekly for 8 weeks. It should be noted that patients will not be aware of the type of medicine. Patients are monitored for 2 months.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Ayatollah Mousavi Hospital in Zanjan

##### Full name of responsible person

Dr. Reza Hassanzadeh Makuei

##### Street address

Ayatollah Mousavi Hospital-Gawazang Road

##### City

Zanjan

##### Province

Zanjan

##### Postal code

2322654235

##### Phone

+98 24 3353 4019

##### Email

Mousavihospital@zums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Zanjan University of Medical Sciences

##### Full name of responsible person

Dr. Alireza Shoghli

##### Street address

Headquarters of Zanjan University of Medical Sciences.Azad Blv.

##### City

Zanjan

##### Province

Zanjan

##### Postal code

1272827222

##### Phone

+98 24 3342 0651

##### Email

info@zums.ac.ir

##### Web page address

[http://zums.ac.ir/index.php?slc\\_lang=fa&sid=24&slct\\_pg\\_id=433](http://zums.ac.ir/index.php?slc_lang=fa&sid=24&slct_pg_id=433)

#### Grant name

#### Grant code / Reference number

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Zanjan University of Medical Sciences

**Proportion provided by this source**

80

**Public or private sector**

Public

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

*empty*

**Country of origin****Type of organization providing the funding**

Academic

**Person responsible for general inquiries****Contact****Name of organization / entity**

Zanjan University of Medical Sciences

**Full name of responsible person**

Dr. Reza Hassanzadeh Makuei

**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Cardiology

**Street address**

Ayatollah Mousavi Hospital-Gavazang Road

**City**

Zanjan

**Province**

Zanjan

**Postal code**

5235255225

**Phone**

+98 24 3353 4019

**Email**

makuei42@yahoo.com

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Zanjan University of Medical Sciences

**Full name of responsible person**

Dr. Reza Hassanzadeh Makuei

**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Cardiology

**Street address**

Ayatollah Mousavi Hospital-Gavazang Road

**City**

Zanjan

**Province**

Zanjan

**Postal code**

5225665855

**Phone**

+98 24 3353 4019

**Email**

makuei42@yahoo.com

**Person responsible for updating data****Contact****Name of organization / entity**

Zanjan University of Medical Sciences

**Full name of responsible person**

Hamid Khederlou

**Position**

Medical Student

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Cardiology

**Street address**

Ayatollah Mousavi Hospital-Gavazang Road

**City**

Zanjan

**Province**

Zanjan

**Postal code**

5288225852

**Phone**

+98 24 3353 4019

**Email**

ham\_khed@yahoo.com

**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

Data files related to the use of medication and medication are also the main implications of sharing.

**When the data will become available and for how long**

The beginning of the access period was 1 year after the publication

**To whom data/document is available**

Data and other study documentation will be available to all individuals and academic and non-academic institutions.

**Under which criteria data/document could be used**

Individuals with data receiving conditions can have the data available after receiving the documented consent of Zanjan University of Medical Sciences

**From where data/document is obtainable**

Visit Zanjan University of Medical Sciences at your personal or e-mail address and get consent for received information.

**What processes are involved for a request to access**

**data/document**

Individuals or institutions, in person or by email, with his introduction and explanation of the purpose of the visit to the Zanjan University of Medical Sciences has the opportunity to have information and can have information within about 1 month.

**Comments**